

Inerts Task Force Report
DRAFT Recommendation on List 3 Inerts
May 13, 2003

Introduction

The NOSB has considered the issues and concerns related to the inert ingredients used in formulated pesticide products since its inception in 1992. (see attached chronology for history of consideration). Since implementation of the NOP regulation in October 2002, there has been concern by producers that lack of available products or disclosure about pesticide ingredient will restrict options for plant protection. This document is provided by the Inerts Task Force to provide guidance to certification agents in implementing the requirement for approved formulations of pesticide products. Task force members included Nancy Ostiguy, Rose Koenig, Kim Burton, Mark King, Miles McEvoy, Eric Sideman, Zea Sonnabend, Brian Baker, and Emily Brown Rosen.

Background

The NOSB recognizes that problems have resulted from the requirement that only List 4 materials may be used in a pesticide product. While this problem will resolve itself through reformulation of products and the reclassification by EPA of List 3 inerts to List 4 or List 1 or 2 inerts, currently farmers are unable to use some pesticides historically used in organic agriculture. Even though EPA expects to complete the reclassification of List 3 inerts exempt from tolerances for food crops by 2006, farmers are faced with a lack of approved inert ingredients in currently available products and, to further complicate the situation, farmers are unable to determine from a product label if a product contains only List 4 materials. This latter problem is a long-standing one that has been partially resolved by the recent approval by EPA of a label that indicates a product meets the National Organic Standards. A second way this problem can be addressed is within the context of the farm plan with oversight by the certification agency. NOSB supports the authority of certification agencies to verify product compliance with the National List. NOSB also urges EPA to help address this problem by providing information as requested by certifiers and NOP/NOSB. NOSB also notes that a requirement for full disclosure of inert ingredients on pesticide labels would greatly aid organic farmers and consumers.

Within this context, the Inerts Task Force attempt to create a procedure to transition from the current situation of approved active ingredients combined with non-List 4 inerts to one where List 4 inerts would replace non-approved inerts. We discussed many alternatives and finally agreed the a list of approved products would be created that met the following criteria:

1. The product has been historically been approved by a now accredited certification agency. "Historically been approved" is intended to mean that the material was permitted by a now accredited certification agency in 2001.
2. Full disclosure of the inert ingredients in the product is made to NOP and NOSB, or permission is granted to EPA to review the product according to criteria (3) and (4) and provide this information to NOP.
3. The product contains no List 1 or 2 materials, and the inerts appear on either EPA List 3, List 4 or are consistent with the NOP National List 7CFR 205.600.
4. The List 3 inert(s) is considered by EPA to be exempt from the requirement of a tolerance for a food crop as specified in 40 CFR180.1001 or 40 CFR180.950.

After discussions with the NOP staff, it was determined that the above solution would not solve the problem because the criteria are in direct conflict with OFPA and the Rule. As such, a Rule change would be necessary before the above criteria could be applied to materials used by farmers. The NOP agreed during the December 20th conference call that the Task Force would be welcome to submit to the NOP for determination of viability any further ideas to resolve the List 3 inerts problem.

The Task Force then developed the following suggestion: "All fully disclosed List 3 inert materials that are considered by EPA to be exempt from the requirement of a tolerance for food crops as specified by 40 CFR 180.1001 or 40 CFR 180.950 allowed for 1 year (from the date of federal register publication)." This was sent to the NOP staff for consideration. No response was ever received concerning the viability of this solution.

Recommendation

1) The NOSB recommends that List 4 inerts remain the approved inerts allowed in pesticides used in organic systems.

(Task Force vote: Yes – 6; No-3)

2) The following shall be considered temporary guidance for the period ending Dec. 2004, to respond to non-compliance on products containing undisclosed inerts: If a product meets the following criterion its use would constitute a minor non-compliance:

- The product has been historically been approved by a now accredited certification agency. "Historically been approved" is intended to mean that the material was permitted by a now accredited certification agency in 2001.

Corrective actions needed for resolution of minor noncompliance

1) A copy of a letter requesting full disclosure of the inert ingredients in the product is sent to the registrant (manufacturer of the formulation) with a deadline for response to the certifier. Disclosure can be made to certifier, or their agent, or achieved by direct assessment by EPA to review the product according to criteria below with resulting report provided to certifier.

Procedures for assessment of corrective action

- 1) Certifier evaluates the status of the inert materials:
 - a. If the inerts appear on EPA List 1 or 2 – prohibit. The grower must cease and desist all use. If further use occurs once notified, this will result in revocation action.
 - b. If inerts are on List 3, certifier will evaluate whether is considered by EPA to be exempt from the requirement of a tolerance for a food crop as specified in 40 CFR 180.1001 or 40 CFR 180.950 - considered a minor noncompliance with date specified for certifier for end of use.
 - c. If the List 3 inert is not exempt from food tolerance, consider minor noncompliance but producer should use up stocks purchased before the date of the notice, and discontinue use.
 - d. If inerts are on List 4 or nonsynthetic, the product is deemed compliant and no further action is needed.
- 2) Producer must demonstrate completion of correction action in compliance with 205.601(m)... by date specified by certifying agent

Registrants with List 3 inert ingredients are encouraged to petition EPA, petition NOP, or reformulate to comply.

**NOSB Inerts Task Force
May 13, 2003**

Historical Information on the Inerts Policy of NOSB/NOP

A. From the Green Book:

During a meeting dated April 11, 1995 the NOSB addressed the "Handling of Inerts Policy". A motion was proposed as follows **"Synthetic inerts shall be reviewed by the NOSB according to the criteria in the OFPA for inclusion on the National List. This shall be handled as an amendment to the National List after the publication of the initial list and after the inerts are identified and evaluated"**. There was discussion regarding the problem of reviewing inerts, specifically trying to attain confidential information necessary for reviewing inerts. It does not appear that this motion was voted on. An amendment was made to the motion above as follows **"The inert priority shall be after the initial national list"**. **This motion failed 4 (Yes), 9 (Opposed) and 1 (abstained).**

A second motion was made **"The NOSB will make every effort to review synthetic inert ingredients for their appropriateness in organic production systems. The NOSB will work with manufacturers of inert substances to obtain full disclosure. This process will take place after the proposed National list and its subsequent Federal Register publication"**. One member commented that if the NOSB doesn't review an inert, then that inert should not be allowed in production. Another member pointed out the difference between full disclosure (for instance, confidentially to the USDA) and public disclosure (to the general public). Others thought the NOSB could be granted an approved status to review confidential information. One member noted that the NOSB does not have statutory authority to be granted this status or review inerts for the program. **The motion passed 10 to 4.**

A member proposed the following motion: **"Inerts on the EPA list 4 are considered to be generally recognized as safe and will be accepted for organic production, with a TAP review and NOSB evaluation according to criteria in the OFPA for those that are synthetic. Inerts proposed for organic production on EPA's List 2 which are potentially toxic and List 3 which are unknown will be compiled by the NOSB and forwarded to the EPA as materials for fast-track review and possible reclassification by them"**. A NOSB member made an amendment to the motion, which was seconded and read **"to strike "with a TAP review and NOSB evaluation according to the criteria on the OFPA for those that are synthetic"**. The member who proposed the original motion stated, **"he opposed this amendment because he wanted to review each inert rather than accept an entire category"**. **The amended motion failed 8 to 6.**

A motion was made to table this discussion which passed 10 (yes) 0? (No) and 2 (abstain).

The Board then passed a resolution on inerts which read: **"Inerts on the EPA list 4 are considered to be generally recognized as safe and will be accepted for organic production, unless an NOSB evaluation finds a specific List 4 inert to be unacceptable. Inerts proposed for organic production on EPA's List 2 which are**

potentially toxic and List 3 which are unknown will be compiled by the NOSB and forwarded to the EPA as materials for fast-track review and possible reclassification”.

B. From the Feb. 10, 1999 NOSB Meeting Minutes Feb. 9-11, 1999

8.5 Criteria for evaluating inert materials for use in organic production and handling.

Inert ingredients on EPA Lists 1 and 2 shall be prohibited for use in organic production and handling effective on the date of implementation of these standards. Synthetic inerts on EPA List 3 shall be prohibited if not specifically allowed by the NOSB. The review of List 3 inerts shall be completed and published by January 1, 2002. Any inert currently in use in organic production which is not approved will be banned within 18 months after the approval process is completed. To that goal, inerts on EPA List 3 used in products that have active ingredients approved for organic production shall be reviewed on a case-by-case basis for possible inclusion on the National List. Inerts on List 4 or considered GRAS (generally recognized as safe) by FDA will generally be allowed unless explicitly recommended for prohibition.

(NOSB, Feb. 1999)

Motion: Joint Crops and Materials Committee. Motion by Eric Sideman.

Inert ingredients on EPA Lists 1 and 2 shall be prohibited for use in organic production and handling effective on the date of implementation of the final rule of NOP. Synthetic inerts on EPA List 3 shall be prohibited if not specifically approved by the NOSB. This approval process will be completed and published by January 1, 2002. Any inert currently in use in organic production that is not approved by the NOSB will be banned within 18 months after the review is completed and published. To that goal, inerts on EPA List 3 used in products that have active ingredients approved for organic production shall be reviewed by the NOSB on a case-by-case basis for possible inclusion on the National List. The NOSB recommends that inerts on List 4 generally be allowed unless explicitly recommended for prohibition.

Second: Joan Gussow

Discussion:

Call for the vote

Vote:

Those In Favor: Unanimous

Those Opposed:

Those Abstaining:

From the text of the FINAL RULE Overview states:

The NOSB has also provided recommendations for the use of synthetic inert ingredients in formulated pesticide products used as production inputs in organic crop or livestock operations. The EPA regulates and maintains the EPA Lists of Inert ingredients used for pesticides. In this final rule, EPA Inerts List 1 and 2 are prohibited, EPA List 3 is also prohibited unless specifically recommended as allowed by the NOSB, and EPA List 4 Inerts are allowed unless specifically prohibited.

In this final rule, only EPA List 4 Inerts are allowed as ingredients in formulated pesticide products used in organic crop and livestock production. The allowance for EPA List 4 Inerts only applies to pesticide formulations. Synthetic ingredients in any formulated products used as organic production inputs, including pesticides, fertilizers, animal drugs and feeds must be included on the National List. There is more information on page 80612-80613 regarding discussion of the National List as it pertains to labeling and uses that should be in compliance with the Federal agencies that oversee the products i.e. EPA or FDA.

Chronological History of Inerts Policy of NOSB/NOP ¹

1987

April 22—US EPA publishes a policy statement on inert ingredients in 52 *Fed. Reg.* 13305 *et seq.* This statement establishes List 1 (inerts of toxicological concern), List 2 (Potentially Toxic Inerts/High Priority for Testing), List 3 (inerts of unknown toxicity), and List 4 (inerts of minimal concern).

1989

November 22—US EPA amends List 4, creating List 4A from the previously established List 4 and adding substances to that list and to the newly established List 4B. (54 *Fed. Reg.* 48314 *et seq.*)

1990

October—Organic Foods Production Act signed into law. The OFPA states:
6517(c)(1) Exemption for Prohibited Substances. The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if
(B) the substance
(ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern;

6518 (k)(1) Requirements. In establishing the proposed National List or proposed amendments to the National List, the Board shall

(2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced;

July 6—Senate report on S.2830 directs the NOSB to work with EPA to obtain information on inert ingredients in pesticides used in organic production (p. 298).

October 22—Conference report on the Farm Bill published. OFPA is contained as Title 21 of the 1990 Farm Bill. The Senate and House versions differed in their treatment of inert ingredients. The Senate version allowed for all inert ingredients, directing the NOSB to obtain information from EPA. House version did not contain a provision that allowed

¹ For detailed history see document submitted by OMRI, May 13, 2003.

for synthetic inert ingredients, essentially prohibiting them. The Conference substitute adopted the House version with an amendment that allows for formulations that have active ingredients and to contain inert ingredients not of toxicological concern (H. 11360-11361).

1992

January—NOSB first appointed.

1993

April 14—NOSB Materials Committee draft Materials Review and Disclosure Policy includes a procedure to gain access to inert ingredients.

November 18—NOP Staff member Michael Hankin provided the CCOF Brand Names List and procedures, with an offer to provide the service to other USDA accredited certifiers.

1994

January 5—NOSB Inerts Task Force meets. NOP staff asserts that inert ingredients do not need to be on the National List in order to be allowed.

April—NOP Staff Ted Rogers and Michael Johnson, and TAP Contractor Zea Sonnabend meet with Kerry Leifer of EPA to discuss inert ingredients in pesticides used in organic agriculture.

September 14—EPA publishes a notice to exempt certain pesticides from registration under section 25(b).

September 26—NOP publishes “Resolution of Focus” and circulates it at the NOSB meeting held in Rohnert Park. This contains a suggested procedure for the NOP to evaluate inert ingredients.

September 28—US EPA adds all substances commonly consumed in foods and are Generally Recognized as Safe to inerts List 4A (59 *Fed. Reg.* 49401).

October 13—NOSB Materials Committee passes an inerts resolution.

December 28—CCOF provides EPA with a list of registered pesticides that have actives allowed under the California Organic Foods Act and requests a list of inert ingredients contained in those formulations. NOSB is copied on this letter.

1995

April—Inerts Task Force members meet with Michael Hankin of NOP.

April 19—NOP staff provides NOSB with the 1988 EPA policy regarding access to confidential business information (CBI) under FIFRA.

July 7—US EPA adds 146 inert ingredients to List 4B. (60 *Fed. Reg.* 35396-35399).

July 28—NOSB inerts task force meets.

September 6—NOSB inerts task force meets; members send out a request for names of registered pesticides used by organic farmers.

October 31—NOSB is presented a list of 144 registered pesticides commonly used by organic farmers, with a request to obtain inert ingredient information.

November 1—NOSB reviews and recommends listing narrow-range petroleum distillates as inert ingredients.

1996

August 3—Food Quality Protection Act (FQPA) signed by President. EPA required to conduct a toxicological reassessment of all inert ingredients in pesticide formulations under a streamlined process. All new inert ingredients exempt from tolerance are to be classified as List 4.

1997

December 16—First proposed NOP Rule published (62 *Fed. Reg.* 65850). USDA proposes allowing all inert ingredients except for List 1, and this extends to all products, not just EPA registered pesticides.

1998

April 30—Comment period closes on first proposed NOP Rule. Inert ingredients are one of the top ten issues receiving comment, with all or nearly all specific comments in opposition to the NOP's proposal.

October 21—List of formulations revised, updated, and presented to NOSB.

December 18—NOSB Chair Robert Anderson sends Jim Jones of EPA the NOSB's suggested steps to obtain and evaluate information on inert ingredients in pesticides used in organic production.

1999

February 11—NOSB makes a unanimous recommendation to prohibit all List 1 and List 2 inert ingredients, to prohibit List 3 inert ingredients unless they are specifically recommended to be allowed, and to allow all List 4 inert ingredients unless the NOSB specifically recommends them to be prohibited. A phase-out clause was deleted from the motion because NOP staff and NOSB members considered such a clause to be inadequate to induce cooperation from registrants and unworkable from the NOP's regulatory point of view. The NOSB also approves a draft of a letter to be mailed to registrants of pesticides used by organic farmers.

May 19—NOSB Crops Committee Chair Eric Sideman provides Keith Jones of the NOP and Kerry Leifer of the EPA a list of over 100 pesticide formulations historically used in organic production.

June 21—Keith Jones sends a letter to pesticide registrants identified asking for cooperation in identifying inert ingredients in order to facilitate TAP reviews. .

Dec. 21, 1999 – NOSB crops Chair, Eric Sideman sent a memo to Keith Jones to ask to send another letter to manufacturers, due to poor response.

2000

March 13—Second National Organic Program proposed rule (65 *Fed. Reg.* 13561-13658).

June 12—Comment period on first proposed rule ends, with comments on inert ingredients policy all either supporting the proposal or wanting case-by-case review of synthetic List 4s. No comments received in support of allowing all List 3 inert ingredients. NOSB comments suggest that NOP involve EPA Pesticide Program staff in the effort to obtain disclosure of inert ingredients.

November —OMRI presents EPA a list of 44 List 3 inert ingredients found in OMRI reviewed and listed products to request that these be considered for reclassification. OMRI operating policy is modified to require all OMRI listed products to contain only inerts on List 4 or the National List by Jan 1 2002.

December 21—NOP Final Rule published (65 *Fed. Reg.* 80548). This allows List 4 inert ingredients in pesticides.

2001

January 19—EPA circulates PR notice on labeling pesticide products that comply with the NOP. This requires inerts to be on List 4 or on the National List.

January— Suppliers with OMRI-listed products that contain List 3's changed to 'conditionally allowed' status and are informed that they will need to either reformulate, petition EPA to reclassify the status of the inert, or petition the NOSB to add the inert ingredients to the National List.

October – EPA provides a ranking of 50 inerts that OMRI and WSDA had requested, and publicly provides this list to the NOSB at the DC meeting. This ranks the inerts on a scale of A-E, with A being already on List 4, and E being – not enough data is available to reclassify (very unlikely by Oct 2002).

2002

April 20—OMRI removes 25 registered pesticides from the *Brand Names List* because they do not comply with the NOP Final Rule.

July 12—EPA provides NOP with a list of candidate pesticide active ingredients.

August – EPA completed tolerance reassessment for a large number of inert as well as active ingredients. EPA List 4 is updated in October 2 on the EPA website.

2003

May 07 -- OMRI reports that 17 of the 25 registered pesticides removed from the *Brand Name Products List* in April 2002 have been restored because they were either reformulated or the EPA reclassified the List 3 inerts that they contained as List 4. Five products discontinued marketing to organic growers, including one pheromone, 3 copper products and a dusting sulfur.